Environmental Assessment

1. **Date:** April 8, 2013

2. **Name of Applicant/Submitter:** Kemira Chemicals, Inc.

3. **Address:** 1000 Parkwood Circle, Suite 500
Atlanta, GA 30339

All communications should be directed to

Dale A. Bauer
Product Stewardship & Regulatory Affairs
Two Phone Nos.: [1] 678-819-4684; [1] 770-722-3762
Email: dale.bauer@kemira.com

Address same as above

4. **Description of Proposed Action:**

a. Requested action:

The proposed action requested in FCN 001272 is to permit the use of 2-propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl-, chloride (1:1), polymer with ethanedial and 2-propenamide as a drainage aid or as a dry and wet strength agent employed in the manufacturing or paper and paperboard in such amount that the finished paper and paperboard will contain the additive at a level not in excess of 2% by weight of the dry fibers in accordance with 21 CFR 176.170 for single use articles.

By adding this copolymer to the wet-end of paper processing, it is assumed that the requirements for a categorical exclusion under 21 CFR 25. 32 are not fulfilled, primarily because of the water solubility of one of the monomers, glyoxal. For this reason, the present environmental assessment was requested by FDA and the data provided herein is related mainly to the FCS itself and glyoxal but the other two monomers, 2-propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride (DADMAC) and acrylamide are addressed.

b. Need of action:

This polymer is intended to replace similar products regulated under 21 CFR 176.170 and FCN 871. Kemira's product is considered a greener product than those currently being marketed both by Kemira and other companies per the original 21 CFR 176.170 citation. The active solid of Kemira's product is 11.5% in comparison to 7.5% of a comparable product. This allows the use of two batches of Kemira's product as compared to three batches of a comparable product resulting in significant energy saved from the manufacturing and lower shipping cost for Kemira's product as compared to these other products currently being marketed in the U.S. In addition, it contains significantly less acrylamide, which is a neurotoxin and a suspect carcinogen and mutagen to man, [Reference 1] than other similarly marketed products.

c. Location of use/disposal:

Kemira's product will be delivered to paper mills for use directly as a drainage aid or as a dry and wet strength agent employed in the manufacturing of paper and paperboard used in direct contact with food. Because of the high water solubility of glyoxal at 600 mg/L at 25°C and a partition coefficient (log Kow) calculated at -1.65 in anhydrous form [Reference 2], a significant amount of the residual, unbound glyoxal may be lost in the initial wash water at the paper mill plant. This is also the case with any residual, unbound acrylamide which is highly water soluble at 2,040 g/l at 25°C and has a partition coefficient of -0.67 - -1.65 [Reference 3]. In addition, DADMAC's monomer is listed as miscible or soluble in water with a partition coefficient as -2.49 [References 4 and 5]. While the FCS itself is provided in a water solution to the paper mill, because it functions as a dry and wet strength additive and, therefore, has a high affinity for solids, very little of this polymer will be washed away in the initial wash water. Most paper mills have their own wastewater treatment plants and a high percentage of the wash water is recycled for reuse by their facilities. The water that does go into wastewater eventually typically undergoes some type of primary treatment followed by a secondary biological treatment and may also undergo a tertiary treatment or a series of settling and polishing ponds prior to discharge. Paper mills generally have their own NPDES permit that must be followed for BOD, COD, SS, and other parameters. Many require a Whole Effluent Toxicity (WET) test to ensure that they are not exhibiting aquatic toxicity for the receiving stream.

The disposal of the finished paper or paperboard product would be expected to occur throughout the U.S. through municipal sold waste landfills, incineration, or through recycling.

5. Identification of substance that is the subject of the proposed action:

General information concerning the chemical identity of the FCS is provided below. A complete description of the FCS is **confidential** and is provided in Part II, Sections A.5. and 6. and Attachments 1 and 2 of Form FDA 3480 to FCN 001272.

a. Nomenclature:

The food-contact substance is a diallyldimethylammonium chloride polymer with acrylamide, reacted with glyoxal. The Chemical Abstract name is 2-propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl, chloride (1:1), polymer with ethanedial and 2-propenamide.

Common name used is modified glyoxalated polyacrylamide or glyoxylated polyacrylamide

b. CAS Registry number: 32555-39-8

c. Molecular weight:

The average molecular weight by weight, Mn, is provided in Part II.A.6 and Attachment 2. This information is considered **confidential.** (See above.)

d. Proposed structural formula:

This information is provided in Part II.A.5 and Attachment 1. This information is considered **confidential.** (See above.)

e. Physical description:

The FCS is a colorless to pale yellow liquid solution, pH 3-3.5, and contains 11.5% solid content. The FCS is a cationic polymer with a high absorption affinity to anionic surfaces (cellulose fiber). Specifically, the FCS attaches to fiber with multiple anchoring points. This type of absorption is typically irreversible and desorption does not occur [Reference 6].

6. Introduction of substances into the environment

a. Introduction of substances into the environment as a result of manufacture

The finished product is normally done in two steps. The acrylamide-DADMAC monomers make an intermediate, called the backbone, which is then glyoxalated in the second step. The manufacturing plants have to meet whatever air and water permits are required by the local, state and Federal governments. Any disposal of old product or production that is off-spec. would be handled through proper waste disposal firms. Therefore, Kemira concludes that there are no special or unique circumstances that apply to the manufacture of the FCS.

b. Introduction of substances into the environment as a result of use/disposal

Because the paper-making process is continuous, then both the wastewater effluent treatment process and release to the environment are continuous. Once the calculated amount is released to the wastewater treatment process, it will undergo probably both primary and secondary treatments in terms of settling, coagulation, flocculation and biological treatment.

If the FCS is added at the dry end, of paper processing, then the categorical exclusion applies because the percentage of the FCS use in the production is ≤2% and the FCS would remain with the food-contact article at >95%.

However, when the FCS is applied to the wet-end phase of the paper process, the maximum dosage is 2% by weight of dry pulp or 40 pounds per ton. Since the upper limit of pulp consistency is about 1%, the concentration in the aqueous phase is up to 200 ppm. In the following calculation, we will assume 2% as the worst case for assessment purposes.

Due to the affinity of the polymer for solids as a wet and dry strength agent, typically 99-100% of the polymer will stay with the paper.

So, the maximum amount that could possibly end up in the water that washes through is:

200 ppm x 0.01 = 2 ppm FCS that could possibly be in the water. Now, much of the water is recycled. Also, when it gets to the wastewater, what does not biodegrade will tend to adsorb onto solids in the wastewater and settle as sludge. Thus, it is estimated that well below 1 ppm could

make it into an effluent. Because the mills must meet their wastewater permits including BOC, COD, SS, Whole Effluent Toxicity, it is not expected that this product will have any significant adverse effect. Furthermore, this is a replacement for either Kemira's existing GPAM products or similar competitive products already in use by these mills.

The FCS contains impurities of glyoxal, DADMAC, and acrylamide. By assuming the pulp consistency is at the upper limit of 1.0%, the expected introduction concentrations (EIC) of three impurities were calculated and summarized below. The results are conservative estimates by applying several "worst case" factors. The calculations are provided in a **Confidential** Report appended to the FCN.

	Fennorez 110 dosage as of dry pulp	EIC
Glyoxal	0.5%	0.6 ppm
	1.0%	1.7 ppm
	2.0%	3.9 ppm
DADMAC	0.5%	0.6 ppm
	1.0%	1.2 ppm
	2.0%	2.3 ppm
Acrylamide	0.5%	0.2 ppb
	1.0%	0.4 ppb
	2.0%	0.8 ppb

Disposal of FCS

1. Landfill

The disposal of the finished paper or paperboard product would be expected to occur throughout the U.S. through municipal solid waste landfills, incineration, or recycling. As of 2009, there were 1,908 municipal solid waste landfills in the US [Reference 7]. According to the US Environmental Protection Agency's (EPA) 2009 update regarding municipal solid waste (MSW) in the United States, 71.6 million tons of paper and paperboard were generated being 29.5% of total MSW generated. 34.98% of 71.6 million tons were containers and packaging materials produced from paper and paperboard. Paper and paperboard containers and packaging were recovered at a rate of 62.4%; however, corrugated containers accounted for most of that amount [Reference 7].

In addition, EPA's regulations require new municipal waste landfills to have composite lines and leachate collection systems to prevent leachate from entering ground and surface water and to have ground water monitoring systems while older landfills, although not required to retrofit liners and leachate collection systems, were required to monitor groundwater and to take corrective action as necessary. Therefore, very insignificant levels of the FCS or the residual monomers are expected to enter the environment as a result of the paper products made with the FCS being land filled.

2. Wastewater

The customer paper mill sites have their own wastewater treatment systems and must meet their NPDES permits as already explained. For sites making the FCS, each has to meet its own air and wastewater permits via scrubbers and treatment systems prior to discharge. In addition, these sites are already making this type of product and the new material is considered "greener" with less energy consumption. Thus, Kemira concludes that there would be no additional impact on these sites from a Federal, State or local emissions regulatory viewpoint.

3. Incineration

The FCS is composed of carbon, oxygen, hydrogen and nitrogen. Kemira concludes that no toxic components would be released upon incineration of the food-contact paper and paperboard containing its FCS and, therefore, would not violate any applicable Federal, State or local emission regulations.

7. Fate of substances released into the environment

a. Physical/chemical properties

The FCS is completely miscible in water. The pH of a FCS solution is between 3.0 - 3.5. An aqueous solution can have between 11.5-13% by weight solids. The FCS solution has a specific gravity of 1.03 g/ml.

An insignificant amount of the FCS would be released in the wash water as mentioned above and any would be treated by the plant's treatment plant and it was previously estimated that less than 1 ppm could make it into the effluent.

If any of the three monomers, acrylamide, DADMAC and glyoxal, were released into the wash water of the paper mill, all three are soluble in water and would be subject to the treatment of waste water at the facility.

b. Environmental depletion mechanisms

No significant effect on the concentration of any substances into air is expected since the polymer is not volatile. In addition, glyoxal is not volatile when in aqueous solutions based on Henry's Law constant, H<33.7 x 10-6 Pa.m3/mol at 15-45 °C [Reference 2]. Upon the use and disposal of food-contact articles containing this FCS, no significant amount of it or any of its monomers or oligomers are expected to be released into the atmosphere. If the food-contact articles are incinerated, the release of carbon dioxide, water, and nitrogen oxides would be released, none of which would significantly affect the air quality based on the total usage of the FCS in food-contact packages.

The FCS is biodegradable based on a study using a Zahn Wellens test which used a comparable resin (but this resin contained more acrylamide that the FCS). The results which showed about 38% biodegradability in 28 days [Reference 8]. Any low molecular weight oligomers and the three monomers released from the food-contact package into the environment would be degraded by soil or water microorganisms or are soluble in water and would be carried into the water ways at extremely low levels. The half-life of biodegradation in water of DADMAC is 360 hours and in addition the same report noted that it is not readily biodegradable in soils {Reference 5]. Finally, glyoxal is readily biodegradable in water showing 82% elimination in 6 days [Reference 2].

Finally, the Estimated Environmental Concentrations (EEC) of the three monomers were calculated by applying "worst case" dilution factor of 20 as suggested by Lonza in FCN 168 EA [Reference 10]. In this EA report, a study by the Swedish National Chemical Inspectorate was cited which employed a dilution factor of 100 even though that report indicated that there was considerable variation of dilution factors between different water recipients [Reference 11]. In addition, the EA also cited a study sponsored by the National Council for Air and Stream Improvement (NCASI) which supported a dilution factor of 20 [Reference 12].

EEC = EIC x dilution factor (20)

Table: EEC results

	FR 110 dosage as of dry pulp	EEC
Glyoxal	0.5%	0.03 ppm
	1.0%	0.09 ppm
	2.0%	0.20 ppm
DADMAC	0.5%	0.03 ppm
	1.0%	0.06 ppm
	2.0%	0.12 ppm
Acrylamide	0.5%	0.01 ppb
	1.0%	0.02 ppb
	2.0%	0.04 ppb

Based on these EEC results, there are no significant adverse effects from these three monomers to the environment.

8. Environmental Effects of Released Substances

As stated above the polymer is biodegradable and, is completely miscible in water, because of its very high affinity for solids, it would not likely be released in water. In a study using fish, the LC50/*Danio rerio*/96 hr is > 10mg/L [Reference 9]. The polymer could not be tested with algae because of it flocculating characteristics of the product. The EC50/for *Daphnia magna*/48 hr was >10 mg/L [Reference 9]. Finally, any sludge containing adsorbed polymer may be applied to landfill..

Because glyoxal is highly soluble and not volatile as stated above, any residual chemical would be released into water. This chemical is produced during cellular metabolism in humans, is found in several edible food products, is readily biodegradable and, is found in various water supplies. It has been tested on various aquatic bacteria, *Pseudokirchneriella subcapitata, Daphnia magna* and four fish species and *Hellianthus tuberousus*. A sample risk characterization for the aquatic environment stated that because the Predicted Environmental concentration (PEC)/Predicted no-effect concentration (PNEC) ratio was less than 1, there were no additional tests required [Reference 2]. Therefore, the release of this chemical does not present a significant environmental concern on the aquatic or soil environments.

Acrylamide, even if released from the polymer, the concentration would be negligible and would present no significant adverse effects on the air, aquatic or soil environments. Acrylamide is also biodegradable.

If DADMAC were released from the polymer, studies reported to the US EPA show that this chemical would not be persistent in the soil, is not toxic to fish or an aquatic organism, does not react with soil microbes, does not compartmentalize between water and oil, and slowly biodegrades [Reference 4].

Therefore, neither polymer nor any of its monomeric impurities would have a significant adverse effect on the environment.

9. Use of Resources and Energy

The production, use and disposal of food-contact articles containing this FCS uses natural resources, such as water, petroleum products, coal, etc. There will be no increase in the use of these resources because this FCS is a substitute for other very similar marketed products. In fact, because this FCS is more concentrated than the standard products, there should be a net reduction in the use of resources, including diesel cost for transportation.

10. Mitigation Measures

As noted above, there are no significant adverse environmental effects on the soil, atmosphere or water expected as a result of the use and disposal of food-contact materials containing this FCS or from any release of oligomers or monomers of the FCS. Therefore, the use of this copolymer as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein, which would require alternative actions to that proposed in this FCN. The alternative of not approving the action proposed would be to continue allowing the use of similar copolymers that contain more acrylamide that are less green in the utilization of natural resources in their production and increased in their transportation costs.

Environmental Assessment for FCN 001272 (continued)

12. List of Preparers

Dale Bauer, B.S. Chemistry, M.S. Environmental Engineering Sciences, MBA
Product Stewardship & Regulatory Affairs, Kemira Chemicals, Inc.

Lu Chen, Ph.D., Ph.D. Chemical Engineering
Senior Research Scientist, Research and Development, Kemira Chemicals, Inc.

13. Certification

The undersigned certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: 4/8/2013

Dale A. Bauer
Product Stewardship & Regulatory Affairs

List References:

1. Toxicological Review of Acrylamide, (CAS No. 79-06-1), U.S. Environmental Protection Agency, Washington, D.C., EPA/635/R-07/009F, March 2010.

2. Opinion on Glyoxal, Scientific Committee on Consumer Products, European Commission, SCCP/0881/05, Adopted by the SCCP during the 4th plenary of 21 June 2005.

3. IUCLID dataset, Acrylamide, European Commission – European Chemicals Bureau, dated 19.2.00.

4. 2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride , (CAS No. 7398-69-8), High Production Volume Information System, U.S. Environmental Production Agency, URL: http://ofmpub.epa.gov/oppthpv/quicksearch.display?pChem=101980

5. IUCLID dataset, 2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, DADMAC HPV Challenge Task Group, dated 27.10.2003.

6. Fleer, G.J., Cohen Stuart, M.A., Scheutiens, J.M.H.M., Cosgrove, T., and Vincent B., *Polymers at Interfaces,* (Pub.) Chapman and Hall, London, 1993.

7. Municipal Solid Waste in the United States, 2009 Facts and Figures, U. S. Environmental Protection Agency, EPA530-R-10-012, December 2010.

8. Inherent Biodegradability: 'Zahn-Wellens/EMPA Test' with Parex 631 NC Resin, NOTOX project 237869, NOTOX B.V., The Netherlands, dated June 26, 1998.

9. Material Safety Data Sheet, FLOPAM WS-72, dated 08/29/2006.

10. EA for FCN 168, Lonza Inc., dated July 27, 2001.

11. Eriksson U et al., Risk Assessment of Slimicides, Kemi Report No. 9195, Swedish National Chemicals Inspectorate (1995).

12. Miner, R. and Unwin, J. Progress in Reducing Water Use and Wastewater Loads in the U.S. Paper Industry, *TAPPI Journal*, pp.127-131, August 1991.